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ORIGINAL ARTICLE

Cemented Femoral Stem Loosening of Hip Arthroplasty: Ten-year Radiographic Analysis

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ABSTRACT

Objectives: *To review the radiological features of femoral stem loosening of cemented hip arthroplasty on plain radiographs and to determine their usefulness.*

Methods: *Between January 2002 and December 2011, 21 patients who had undergone revision of hip arthroplasty in a regional hospital in Hong Kong with cemented femoral stem loosening were retrospectively studied with respect to plain radiography indicating stem loosening. Thirty-three patients who had hip arthroplasty with cemented femoral stems between January 2004 and December 2007, without clinical suspicion of stem loosening, were included as controls. Statistical analysis was performed on the six specific radiological features: (1) osteolysis (non-linear radiolucency of >5 mm), (2) increased cement-bone interface of >2 mm, (3) radiolucent line between stem and cement at superolateral part of stem of >2 mm (subsidence), (4) radiolucent line between stem and cement in all Gruen zones of >1 mm, (5) sclerosis and thickening of bone at level of stem tip, and (6) inadequate cementation (grade C or D according to Barrack et al or cement thickness of <2 mm in any Gruen zone).*

Results: *Of the six radiological features, increased cement-bone interface, subsidence, and inadequate cementation were indicative of cemented femoral stem loosening, respective adjusted odds ratios being 17.4 (p = 0.003), 10.3 (p = 0.026), and 7.5 (p = 0.040). Inter-rater consistency was highest for subsidence and increased cement-bone interface (with kappa values of 0.60 and 0.56, respectively).*

Conclusion: *Features of increased cement-bone interface, subsidence, and inadequate cementation on plain radiographs are the strongest indicators of cemented femoral stem loosening.*

Key Words: *Arthroplasty, replacement, hip; Bone cements; Femur; Prosthesis failure; Radiography*

中文摘要

髖關節置換術後骨水泥型股骨柄假體的鬆動：分析十年病例的放射學研究

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目的：回顧髖關節置換術中水泥股骨柄鬆動在X綫平片的放射學特徵，以及探討這些特徵是否有用。

方法：回顧研究從2002年1月至2011年12月期間於香港一所分區醫院中，21名曾進行髖關節置換術而

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出現水泥股骨柄鬆動的X綫平片。對照組是2004年1月至2007年12月期間進行水泥股骨柄髖關節置換術但無股骨柄鬆動可疑性的33名病人。並按以下六項具體的放射性特徵進行統計分析：（1）骨溶解（多於5毫米的非線性透射）、（2）水泥—骨界面增寬多於2毫米、（3）股骨柄上外側假體與水泥間的透亮帶多於2毫米（下沉）、（4）在所有Gruen分區內股骨柄假體與水泥的透亮帶多於1毫米、（5）股骨柄尖端骨質硬化及增厚及（6）膠結不足（按Barrack分級為C或D級，或在任何Gruen分區內水泥厚度少於2毫米）。

結果：六項放射學特徵中，水泥—骨界面增寬、假體下沉及膠結不足均提示水泥股骨柄假體有鬆動，校正後比數比分別為17.4（$p = 0.003$）、10.3（$p = 0.026$）及7.5（$p = 0.040$）。其中假體下沉和水泥—骨界面增寬兩項特徵的評估者間一致性為最高（kappa值分別為0.60和0.56)。

結論：本研究發現X線平片中水泥—骨界面增寬、假體下沉及膠結不足為提示水泥股骨柄假體鬆動的最有效指徵。

INTRODUCTION

Nearly a decade has passed since the earliest attempt at hip replacement.[1] In 1923, Smith-Petersen introduced glass mould arthroplasty,[2,3] but all cases failed as the glass broke within a few months. In 1958, Sir John Charnley performed the first total hip arthroplasty with a cemented femoral stem and acetabulum cup.[4]

In the 1980s, up to one-third appeared to endure loosening within 10 years of the operation.[5] Throughout the years, there were advances in surgical techniques, cementation techniques and materials used in hip arthroplasty, yet femoral stem loosening is still one of the commonest complications. According to the Swedish Hip Arthroplasty Register 2010,[6] the postoperative revision rate for cemented femoral stem hip arthroplasty due to loosening was 1.5% at 10 years and 4.8% at 15 years.

There are various radiological indicators of femoral stem loosening, including: osteolysis (non-linear radiolucency of >5 mm), increased cement-bone interface of >2 mm, radiolucent line between superolateral part of stem and cement of >2 mm (subsidence), radiolucent line between stem and cement in all Gruen zones of >1 mm, sclerosis and thickening of bone at level of stem tip, inadequate cementation (grade C or D according to Barrack et al[7] or cement thickness of <2 mm in any Gruen zone). This study aimed to review these specific features indicative of cemented femoral stem loosening on plain radiographs and determine their usefulness.

METHODS

This study was an unmatched case-control study. The cases and controls were retrieved from the Clinical Data Analysis and Reporting System of the Hospital Authority of Hong Kong.

For the case group, patients with revision hip arthroplasty performed in any regional hospital between 1 January 2002 and 31 December 2011 were studied. The corresponding operation record was retrieved from the Clinical Management System (CMS) of the Hospital Authority of Hong Kong. Only those with initial operation being hip arthroplasty with cemented femoral stem, and had documented operative diagnosis of cemented femoral stem loosening were included. The state of acetabular component was not taken into account. The anteroposterior plain radiographs of the hip and pelvis taken at the time when there was a clinical suspicion of loosening were assessed.

The controls were patients who had hip arthroplasty with cemented femoral stems performed between 1 January 2004 and 31 December 2007. The corresponding CMS notes until 30 June 2012 were reviewed. Thus, only patients with no major complaints and who had survived till 30 June 2012 were included as controls. Patients who had passed away, or in whom there was suspected or confirmed loosening, dislocation, periprosthetic fracture, or a history of a revision operation were excluded. The most recent anteroposterior plain radiographs of the hip and pelvis taken in the first 3 years after the operation were assessed.

The cases and controls were indexed and randomised using a randomisation table. An assessment form was prepared with the patient's Hong Kong identity card number, the date of the plain radiograph reviewed and its laterality. The radiological assessments were carried out by two radiologists who were blinded to the clinical outcomes.

The presence of six specific radiological features were searched for and recorded on a specially designed form. These were: (1) osteolysis (non-linear radiolucency of >5 mm), (2) a cement-bone interface of >2 mm, (3) a radiolucent line of >2 mm between the superolateral part of stem and the cement (i.e. subsidence), (4) a radiolucent line of >1 mm between the stem and the cement in all Gruen zones, (5) sclerosis and thickening of bone at the level of the stem tip, and (6) inadequate cementation (grade C or D according to grading system of Barrack et al[7] or cement thickness of <2 mm in any Gruen zone).

Table 1. Demographic data of case and control group.

Demographics	Cases (n = 21)	Controls (n = 33)
Males : females	17 : 4	10 : 23
Age (years)		
Mean	60	70
Range	33-87	29-86
Median	58	74
Standard deviation	12.8	12.3
>65	7 (33%)	26 (79%)
≤65	14 (67%)	7 (21%)
Diagnosis		
Osteoarthritis	1 (5%)	17 (52%)
Avascular necrosis	16 (76%)	9 (27%)
Ankylosing spondylitis	2 (10%)	2 (6%)
Others	2 (10%)	5 (15%)

The degree of association between the six specific radiological features on plain radiographs and a definite diagnosis of cemented femoral stem loosening were evaluated by binary logistic regression. An adjusted diagnostic odds ratio (OR) was calculated for each specific feature and the level of statistical significance set at 5%. Kappa values were calculated to determine the inter-rater consistency of these radiological findings. All statistical analyses were performed by using the Statistical Package for the Social Sciences (Windows version 18.0; SPSS Inc, Chicago [IL], US).

RESULTS

In all, 23 patients with cemented femoral stem failure were identified based on our inclusion criteria, two patients were excluded due to a history of trauma resulting in periprosthetic fractures. In the control group there were 33 patients. Demographic data of these patients are shown in Table 1.

The sensitivity, specificity, positive and negative predictive values of the six designated radiological features are shown in Table 2.

With univariate analysis, osteolysis, inadequate cementation, increased cement-bone interface, and subsidence were shown to be statistically significant; the respective diagnostic ORs were 9.1 (p = 0.001), 8.0 (p = 0.001), 6.2 (p = 0.003), and 6.2 (p = 0.010). These results are illustrated in Table 3. These four radiological features were then further evaluated using

Table 2. Sensitivity, specificity, positive and negative predictive values of the six radiological features.

Radiological feature	True positive	True negative	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Osteolysis	10	30	47.6	90.9	76.9	73.2
Increased cement-bone interface >2 mm	11	28	52.4	84.8	68.8	73.7
Subsidence	8	30	38.1	90.9	72.7	69.8
Radiolucent line between stem and cement in all Gruen zones	3	31	14.3	93.9	60.0	63.3
Sclerosis and thickening of bone at level of stem tip	1	33	4.8	100.0	100.0	62.3
Inadequate cementation	11	29	52.4	87.9	73.3	74.4

Table 3. Univariate analysis of the six radiological features.

Radiological feature	Odds ratio	95% Confidence interval	p Value
Osteolysis	9.1	2.1-39.3	0.001
Increased cement-bone interface >2 mm	6.2	1.7-22.2	0.003
Subsidence	6.2	1.4-27.0	0.010
Radiolucent line between stem and cement in all Gruen zones	2.6	0.4-17.0	0.309
Sclerosis and thickening of bone at level of stem tip	0.4	0.3-0.5	0.206
Inadequate cementation	8.0	2.1-30.8	0.001

Table 4. Multivariate analysis of the six radiological features.

Radiological feature	Odds ratio	95% Confidence interval	p Value
Osteolysis	6.4	0.9-44.4	0.060
Increased cement-bone interface >2 mm	17.4	2.6-117.3	0.003
Subsidence	10.3	1.3-79.3	0.026
Inadequate cementation	7.5	1.1-51.2	0.040

Table 5. Inter-rater consistency.

Radiological feature	Kappa value
Osteolysis	0.28
Increased cement-bone interface >2 mm	0.56
Subsidence	0.60
Radiolucent line between stem and cement in all Gruen zones	0.25
Sclerosis and thickening of bone at level of stem tip	N/A*
Inadequate cementation	0.34

* The kappa value cannot be calculated since one set of data yielded zero and unable to be analysed by SPSS 18.0.

multivariate regression analysis as shown in Table 4. This indicated that increased cement-bone interface, subsidence, and inadequate cementation were more indicative of cemented femoral stem loosening; the adjusted ORs being 17.4 (p = 0.003), 10.3 (p = 0.026), and 7.5 (p = 0.040), while the OR for osteolysis of 6.4 was statistically insignificant (p=0.060).

Inter-rater consistency was highest for subsidence and increased cement-bone interface (with kappa values being 0.60 and 0.56, respectively) as shown in Table 5.

DISCUSSION

There had been well-established literature on the radiological features of loosening since the 1970s. Brand et al[8] showed that changing the radiological definition of loosening can double its reported frequency. Kramhøft et al[9] found high intra- and inter-observer variability, with kappa values ranging from 0.737 to 0.800 in the radiological assessment of the stem. There were differences in the interpretation of radiolucencies and migration which lead to difficulty in comparing outcomes in different studies.[10,11] Yet few papers compare the ORs of each radiological feature.

1. Osteolysis (non-linear radiolucency of >5 mm)

Charnley[12] observed osteolysis at Teflon cup arthroplasties in 1963, but also in stable components.[13] Nowadays, osteolysis is usually defined as a non-linear radiolucency of >5 mm.[14] There were various theories and postulations for the mechanism of osteolysis. The most accepted theory was that particulate wear debris resulted in an inflammatory reaction entailing macrophages and a chain of chemical-mediated reactions.[15-17] These ultimately resulted in bone resorption by osteoclasts and monocytes.[18,19] In femoral stem loosening, the particles generated would migrate down the medullary canal between the bone cement, following the path of least resistance. Intracapsular pressure also acted as a driving force.

From the literature, osteolysis rates range from 5% to 70%.[20-25] The wide range was likely due to differences in prosthesis designs, techniques, approaches, surgical skills, as well as demographic and technical factors. Huddleston[20] studied 260 Charnley femoral components with aseptic loosening, and determined an osteolysis frequency of 23.8%. Mulroy and Harris[21] radiologically reviewed 105 hips with four different types of prosthesis in 93 patients after 10 to 12.7 years, and reported a frequency of localised osteolysis of 6.8%. Maloney et al[22] reported that osteolysis occurred in 70% of their 25 hips 5 years post-surgery, and was not related to age, gender, or diagnosis. Joshi et al[23] reviewed 249 Charnley arthroplasties performed by a single surgeon with a minimum follow-up of 10 years, and noted a femoral osteolysis frequency of 6.4%.

In our study, the OR was high in the univariate analysis (OR = 9.1, p = 0.001) despite a low inter-rater consistency (kappa value = 0.28 only). Upon multivariate analysis, the OR was 6.4, though statistically insignificant (p = 0.060). This suggests that the association between osteolysis and femoral stem loosening might be subject to confounding factors (Figure 1).

2. Increased cement-bone interface of >2 mm

Increased cement bone interface had been identified as a feature of loosening,[26-31] and was categorised as ‘indicating loosening’ by Harris et al in 1982.[32]

Gruen et al[33] in 1979 reported an 11.1% frequency among the 389 hip arthroplasties, and suggested the pistoning mode of failure (mode Ib), in that the applied

Figure 1. A 46-year-old man with a total hip replacement performed in 1993 for avascular necrosis has osteolysis at Gruen zones 2 and 6 (arrows) 9 years postoperatively.

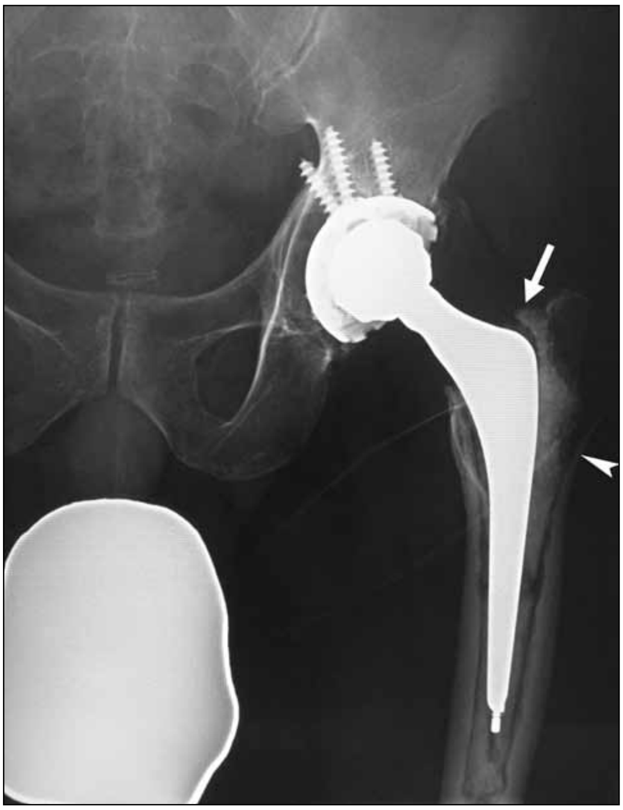

Figure 2. A 66-year-old man with total hip replacement performed in 1995 for avascular necrosis yields an increase in cement-bone interface, subsidence (arrow), and osteolysis at Gruen zone 1 (arrowhead) 7 years postoperatively.

stress appeared to disrupt the mechanical bond at the cement-bone interface with subsequent slip.

At the bone-cement interface, a thin fibrous layer may form as a response to local necrosis of osseous tissue due to the heat of the cement-polymerisation. It becomes stable by 2 years. On radiographs, this layer is seen as a lucent zone that should be <2 mm, and delimited from adjacent bone by a thin sclerotic demarcation line that runs parallel to it. Non-progressive radiolucent zones not exceeding 2 mm at the cement interfaces are considered normal.[34-36]

Ebramzadeh et al[37] reviewed 860 cemented total hip arthroplasties performed by a single surgeon, with annual follow-ups and of up to 27.6 years. Most common sites were at Gruen zones 1 and 7 (18.1% and 25.3%, respectively).

In our study, the OR was 17.4 (p = 0.003) in the multivariate analysis, and was the highest among the six specific radiological features. The inter-rater consistency was relatively high (kappa value = 0.56) [Figure 2]. In a similar study by Chambers et al,[38] the cement-bone interface lucency had an OR of 4.0 (p = 0.007).

3. Radiolucent line between the superolateral part of stem and cement of >2 mm (subsidence)

Subsidence was described as a change in stem position and included as a feature of loosening in previous studies.[39-42]

Gruen et al[33] in 1979 described incomplete cement encapsulation or subsequent loss of the proximal-medial acrylic support from axial loading which resulted in distal displacement of the stem, radiolucent zone at proximal-lateral zone (zone 1), and punch-out fractures at the cement at tip of the stem. He described it as pistoning behaviour (mode Ia).[33]

Jasty et al[43] suggested that failure of cemented femoral components was initiated by debonding at the cement-prosthesis interface. Harris[44] described subsidence as first sign of debonding between the femoral component and cement. Berry et al[45] reviewed 297 Charnley total hips with follow-up of 20 years or until revision or death. There was no survival difference if the radiolucent line between superolateral border of the stem and cement was less than 2 mm, but much poorer outcome if more than 2 mm.[45]

In our study, the OR was 10.3 (p = 0.026) in the multivariate analysis. Inter-rater consistency was highest among the six signs with a kappa value of 0.60 (Figure 3).

4. Radiolucent line of >1 mm between the stem and cement in all Gruen zones

Gruen et al[33] used zonal description at the femoral component and described cement-embedded pistoning within the bone as mode Ib failure.

If the radiolucency occurred immediately after the operation, it might be due to the poor cementing technique. If the radiolucency was more than 1 mm, or progressive and not seen previously, it could indicate implant loosening.[46]

In the Ebramzadeh et al's study,[37] 22.2% (191 of 860) developed a radiolucent line between the stem and cement, with 14.0% at zone 1 and 2.0% at zone 7.

In our study, the OR was statistically insignificant (p = 0.309). Inter-rater consistency was only fair with a kappa value of 0.25. In the Chambers et al's study,[38] the OR was also statistically insignificant (p = 0.92).

5. Sclerosis and thickening of bone at the level of the stem tip

If there was medial and lateral toggle of the distal end of the stem, the end lacked support and bone reaction would develop with sclerosis and thickening. This was described as the calcar pivot mechanism (mode III) by Gruen et al.[33]

In our study, the OR for this was statistically insignificant (p = 0.206) [Figure 4].

Figure 3. A 50-year-old man with a total hip replacement performed in 2004 for avascular necrosis has subsidence (arrow), increased cement-bone interface, and osteolysis at Gruen zone 3 (arrowhead) 6 years after his surgery.

Figure 4. A 69-year-old man with total hip replacement performed for osteoarthritis in 2000, has thickening at lateral cortex with osteolysis at zone 3 (arrow) 4 years postoperatively.

6. Inadequate cementation (grade C or D according to Barrack et al or cement thickness of <2 mm in any Gruen zone)

In 1992, Barrack et al[7] described four grades of cementing quality for hip arthroplasty in plain radiographs. Grade A meant complete filling of the medullary cavity by cement, a so-called 'whiteout' at the cement-bone interface. Grade B meant slight radiolucency at the cement-bone interface. Grade C meant radiolucency involving 50 to 99% of the cement-bone interface or a defective or incomplete cement mantle. Finally, grade D meant definite radiolucency at the cement-bone interface of 100% in any projection, or a failure to fill the canal with cement such that the tip of the stem was not covered.

Mulroy et al[47] reported that a femoral cement mantle of <1 mm or with a defect was associated with early loosening. Jasty et al[48] noted that cement voids and stem abutments against the femur (indicating an inadequate cement mantle) were associated with loosening.

In our study, the OR for inadequate cementation was 7.5 ($p = 0.040$) in the multivariate analysis. The inter-rater consistency was only fair with a kappa value of 0.34. In the Chambers et al's study,[38] the OR for inadequate cementation with Barrack grades C or D was 9.5 ($p < 0.0001$) and cement mantle of <2 mm was as high as 21.0 ($p = 0.0001$) [Figure 5].

Figure 5. A 33-year-old man with total hip replacement performed for avascular necrosis in 1997, has inadequate cementation predominantly over zones 2 and 3 (arrowhead), and an increased cement-bone interface at zones 5 to 7 (arrow) at 10-year post-surgery.

Cemented Femoral Stem Loosening

Most studies in the literature used plain radiographs from the early postoperative period to predict any future loosening. We reviewed radiographs obtained at the time loosening was clinical suspected and looked for the presence of specific signs. The OR calculated was thus the diagnostic OR.

In our study, some anteroposterior and lateral radiographs were either not well taken or not available, especially those in the early years. Therefore, in this study only anteroposterior plain radiographs were chosen for review.

Despite including 10 years of femoral stem loosening cases from January 2002 to December 2011, only 21 fulfilled the inclusion criteria. In the control group, there were only 33 cases from January 2004 to December 2007. Those who had hip arthroplasties performed in recent years were not included as controls, as a longer follow-up time was needed to distinguish them from possible cases of loosening. The small sample size for both cases and controls also limited subgroup analysis.

The diagnosis of loosening depends on intraoperative findings. Whether certain radiological features exist is somehow subjective, and depends on the experience of the reviewing radiologists.

With the popularisation of plain radiographs and other available imaging modalities, loosening or migration of implants could be picked up at an earlier stage, so that prompt investigation and treatment could prevent further complications. The presence of one or more features does not necessarily represent loosening, if it appears early in postoperative radiographs and does not progress, as it may be related to the specific implant design or surgical technique. Therefore, regular follow-up and serial radiography is still of utmost importance to monitor any change in implant position. In daily practice, clinicians may also encounter situations in which previous plain radiographs were not available for assessing interval changes. This study helps identify the radiological features for clinicians to assess when looking for possible femoral stem loosening.

CONCLUSION

Among the features on plain radiographs, patients with an increased cement-bone interface have a 17.4 times odds (risk) of suffering from cemented femoral stem loosening compared to patients without that feature; those with subsidence or inadequate cementation have a risk of 10.3 and 7.5, respectively. We conclude that features suggesting an increased cement-bone interface, subsidence, and inadequate cementation on plain radiographs are the strongest indicators of cemented femoral stem loosening.

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